



**Health Care Regulation and Quality Improvement**

800 NE Oregon Street, Suite 465

Portland, Oregon 97232

971-673-0540

971-673-0556 (Fax)

The purpose of this letter is to outline the process you need to complete in order to obtain certification as a rural health clinic.

For assistance with determining eligibility or if you have questions about the rural health clinic program please contact the Clinic Technical Assistance Specialist at the Office of Rural Health, 503-494-4450 or email to [ruralweb@ohsu.edu](mailto:ruralweb@ohsu.edu). Information is also available on the Office of Rural Health Website at:  
<https://www.ohsu.edu/oregon-office-of-rural-health>

The Health Care Regulation and Quality Improvement Section of the Oregon Health Authority has an agreement with the U.S. Department of Health and Human Services, Center for Medicare and Medicaid Services (CMS) formerly Health Care Financing Administration (HCFA), to assist in determining whether health care facilities meet, and continue to meet, required conditions of participation.

If you wish to participate, and if you believe your facility substantially meets the required conditions, please complete and return these forms:

- (1) ***CMS 1561 A - Health Insurance Benefit Agreement (2 signed originals required) available online:***  
***<http://www.cms.gov/cmsforms/downloads/cms1561a.pdf>***
- (2) ***CMS 29 - Request to Establish Eligibility available online:***  
***<http://www.cms.hhs.gov/cmsforms/downloads/CMS29.pdf>***
- (3) **HHS 690 - Assurance of Compliance with Title VI of the Civil Rights Act (2 signed original copies required) and the Civil Rights Packet available online\*:** **<https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf>**  
**\*(If the RHC is applying to be provider based)**

In addition to the required forms and accompanying instructions, you can find a copy

of the regulations that cover all of the requirements of the Medicare program on-line at: <https://www.cms.gov/files/document/appendix-g-state-operations-manual>

These requirements include the standards, which must be met in regard to the care of patients and the principles of reimbursement for provider costs. To qualify for Medicare payments your facility must be in compliance with the Medicare conditions for certification and the requirements for reimbursement, including financial solvency.

After the completed and signed documents have been submitted, you must submit a **written request** to our office for a survey of your clinic. This will be an unannounced on-site survey. Prior to this survey being scheduled, some essential steps must be completed:

- **A Medicare certification survey cannot be conducted until we have received approval of your enrollment application (CMS 855A) from the fiscal intermediary (FI) or insurance carrier.** Our office will receive a copy of your 855A form from the FI, however, you must send the original 855A form to your FI.
- **Please contact the Noridian Government Benefits Administrator, <https://med.noridianmedicare.com/>**
- **The on-site survey cannot be conducted until a written request stating that you are in compliance with the Medicare Conditions for Certification as a rural health clinic and have provided services has been received and reviewed by our office.** This written request should be received in our office at least two weeks prior to your expected date of full operation.
- **Services must have been provided to one or more patients before the on-site survey can be conducted.** These patients do not need to be Medicare beneficiaries.
- **You must have and display a current Oregon license to perform the required laboratory tests for the purpose of diagnosis and treatment or assessment of an individual's health.** For information regarding this license, you may contact the Center for Public Health Laboratories, laboratory Licensing Section. Their contact number is 503-693-4100, you may also view their website at: <https://www.oregon.gov/oha/PH/LABORATORYSERVICES/CLINICALLABORATORYREGULATION/Pages/index.aspx>

Services provided **prior** to the certification date will not be eligible for Medicare Reimbursement. The date of certification can be no earlier than the date of the onsite survey (if you are in complete compliance with all Medicare regulations), or the date of

an acceptable plan of correction if your clinic is cited for deficiencies during the onsite survey.

As part of the survey process, the surveyor will inspect the clinic; conduct interviews with you and members of your staff, review onsite documentation, and other tasks necessary to determine the extent to which your facility is in compliance with the conditions for certification.

Following the survey and based on the findings at that time, our office will recommend to the Department of Health and Human Services whether your facility should participate in the rural health clinic program. Once it has been determined that **all** Medicare requirements have been met, the Health Insurance Benefit Agreement will be countersigned and a copy will be returned to you, along with the notification that your clinic has been approved as a rural health clinic.

You are required to notify this office if at any time you transfer ownership to another owner, an ownership group, or to a lessee. Please be advised, based on regulations at 42 CFR 489.19 the courts have upheld CMS's right to hold a new owner responsible for overpayment to a previous owner. CMS has the right to recoup from the buyer even when a sales agreement specifically states that the buyer will not accept the liability of the seller. The enclosed information has been prepared to outline the effect of a new owner's acceptance or refusal of assignment of an existing Medicare provider agreement.

Those institutions and agencies, which are denied certification in the program, will be notified and given the reasons for the denial and information about their rights to appeal the decision. Please do not hesitate to call this office if you have any questions.

Please note: There is now an accreditation option for Rural Health Clinics, AAAASF or The Compliance Team. Thus, similar to other facility types that have an alternative option, HCRQI will now need to balance this work with other State and Federal priorities. We have clear direction from CMS to ensure that the highest priority Federal survey work is completed before we turn to any initial surveys.

After thorough review, we have come to the conclusion that we do have the current capacity to continue to offer RHCs an initial certification survey. However, although we will make every effort to offer timely surveys, there may be some waiting as we balance this work on an ongoing basis with our other higher priority and complaint surveys. We recommend that those clinics that would like to pursue a potentially quicker certification should contact these accreditation organizations to explore all options.

HCRQI understands that Rural Health Clinics often face a variety of obstacles on the

path to getting established and we have made a commitment to assist those communities with serious access to care issues.

Sincerely,

HCRQI Staff  
Client Care Surveyor  
CMS Representative  
Oregon Health Authority  
Public Health Division  
Health Care Regulation and Quality Improvement

**If you need this material in an alternate format, please call our office at (971) 673-0540 or TTY (971) 673-0556.**

## **MEDICARE PROVIDER AGREEMENTS AND CHANGES OF OWNERSHIP**

### **NEW OWNER ACCEPTS ASSIGNMENT OF PREVIOUS OWNER'S PROVIDER AGREEMENT**

Consequences: New owner is given previous owner's provider number and agreement. There is no break in coverage, but new owner becomes liable for all penalties, sanctions, and liabilities imposed on or incurred by previous owner. If, after accepting the assignment, the new owner subsequently elects to terminate its provider agreement, it must (under the provisions of section 1866(b)(1) of the Act) file a written notice of its intention, and follow the procedures for voluntary termination.

- The regulations specify that when there is a change of ownership, the existing Medicare agreement is automatically assigned to the new owner (42 CFR 489.18(c)). New owners are not required to accept assignment of the agreement but they must state their refusal in writing.

### **NEW OWNER REFUSES ASSIGNMENT OF PREVIOUS OWNER'S PROVIDER AGREEMENT**

Consequences: The previous owner's provider agreement terminates on the date the previous owner ceased doing business.

- **NEW OWNER DOESN'T WANT TO PARTICIPATE IN PROGRAM**  
Consequences: New owner has, in effect, purchased only capital assets. The business ceased being a Medicare provider on the last day of business of the previous owner.
- **NEW OWNER WANTS TO PARTICIPATE IN PROGRAM**  
Consequences: New owner will have to request to participate in the program, undergo an initial survey, meet the participation requirements, and be certified. There will be no Medicare coverage or payments until the provider is certified, and no retroactive payments for the period between the termination of the previous owner's provider agreement and the commencement of the new owner's provider agreement. However, the new owner is free of any penalties, sanctions, or liabilities imposed on or incurred by the previous owner.

Y = Yes

N = No

NA = Not Applicable

(Please circle appropriate response)

## RURAL HEALTH CLINIC CHECKLIST

### **I. Location of the Clinic**

1. Is the clinic located in a rural area (one that wasn't designated as an urban area during the most recent census)? Y / N / NA
  
2. Is the clinic located in a shortage area under one of the following criteria designated or updated in the current or prior three years?  
Y / N / NA
  - Health Professional Shortage Area (HPSA); Y / N / NA
  - Medically Underserved Area (MUA). Y / N / NA

### **II. Licensure, Certification or Registration of Personnel**

1. Are licenses of physicians (and nurse practitioners if applicable) current, and are copies kept at the clinic? Y / N / NA
  
2. Are physician assistants currently licensed, and are copies of their licenses kept in the clinic? Y / N / NA & Y / N / NA
  
3. If mid-level practitioners have limited permits to take x-rays, are copies of these permits kept in the clinic, and are they current? Y / N / NA
  
4. If other health care personnel requiring licensing or certification work in the clinic (RNs, LPNs, CNAs), are copies of their current licenses or copies of their CAN certificates kept in the clinic? Y / N / NA

### **III. Staff and Staff Responsibilities**

1. Is there a physician who has agreed to serve as, and is functioning as, Medical Director? Y / N / NA

This means that the physician:

- provides medical direction for the clinic's health care activities; Y / N / NA
- provides consultation for the health care staff; Y / N / NA

- provides medical supervision of the health care staff; Y / N / NA
  - participates in developing, executing, and at least annually reviewing the clinic's written policies and the services provided to Federal Program patients; Y / N / NA
  - periodically reviews the clinic's patient records; Y / N / NA
  - provides medical care services and medical orders to the patients of the clinic; Y / N / NA
  - is present in the clinic at least once in every two weeks, and is available by telephone. Y / N / NA
2. Is there at least one physician and one mid-level practitioner (nurse practitioner or physician assistant) on the staff? Y / N / NA
3. Is there a physician or a mid-level practitioner on duty at all times when the clinic is in operation? Y / N / NA
4. Is the mid-level practitioner on duty at least 50% of the time the clinic is open for business? Y / N / NA
5. Does the mid-level practitioner:
- participate in the development, execution, and periodic review of the written policies; Y / N / NA
  - participate with the physician in a periodic review of the patients' health records; Y / N / NA
  - provide services in accordance with the clinic's policies; Y / N / NA
  - arrange for, or refer patients to, needed services that cannot be provided at the clinic; Y / N / NA
  - assure that adequate patient health records are maintained and transferred as required when patients are referred elsewhere? Y / N / NA

#### **IV. Direct Services**

1. Does the clinic provide diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office Y / N / NA? For example:
- medical history; Y / N / NA
  - physical examination; Y / N / NA
  - assessment of health status; Y / N / NA
  - treatment for a variety of medical conditions. Y / N / NA
2. Does the clinic have a laboratory which provides the following basic services:

- chemical examinations of urine by stick or tablet, including urine ketones; Y / N / NA
  - hemoglobin or hematocrit; Y / N / NA
  - blood sugar; Y / N / NA
  - examinations of stool specimens for occult blood; Y / N / NA
  - pregnancy tests; Y / N / NA
  - primary culturing for transmittal to certified laboratory(ies); Y / N / NA
3. Does the clinic provide medical emergency procedures as a first response to common life-threatening injuries and acute illnesses and have available the drugs and biologicals commonly used in life saving procedures? Y / N / NA

**V. Services Provided Through Arrangements**

1. Does the clinic have a written or verbal agreement with Medicare providers to furnish other services to patients (such providers would be hospitals, consulting physicians, Laboratories, etc.)? Y / N / NA
2. Does the clinic refer patients to the above when necessary? Y / N / NA

**VI. Patient Health Records**

1. Who is the designated staff person who is responsible for the medical records?

Name Title \_\_\_\_\_

2. Does this person have the responsibility for:
- maintaining the records; Y / N / NA
  - ensuring that they are completely and accurately documented, readily accessible and systematically organized? Y / N / NA
3. Is there a written policy/procedure addressing patient health records? Y / N / NA
4. Does the written policy include the use and removal of records from the clinic and the conditions for release of information? Y / N / NA
5. Is the patient's written consent required before information is released (except for release authorized by law)? Y / N / NA
6. Are the records kept for at least seven (7) years from last date of entry? Y / N / NA

7. Do the records include, as applicable:

- identification and social data; Y / N / NA
- evidence of consent forms; Y / N / NA
- pertinent medical history; Y / N / NA
- assessment of health status and care needs of the patient; Y / N / NA
- brief summary of each episode, including disposition and instructions to the patient; Y / N / NA
- reports of physical examinations; Y / N / NA
- laboratory test results; Y / N / NA
- consultative findings; Y / N / NA
- physicians' orders; Y / N / NA
- reports of treatments and medications; Y / N / NA
- signatures of the physician(s) and other health care professionals?  
Y / N / NA

8. Are the records protected against loss, destruction, or unauthorized use?  
Y / N / NA

9. Are all persons that do not have a legitimate reason for accessing the medical records prevented from the possibility of doing so? Y / N / NA

## **VII. Program Evaluation**

1. Does the clinic carry out, or arrange for, an evaluation of its total program? Y /  
N / NA

2. Is this evaluation conducted at least annually? Y / N / NA

3. Is this evaluation documented? Y / N / NA

4. Does the evaluation include a review of:

- the utilization of the clinic's services, including the number of patients served and the volume of services; Y / N / NA
- a representative sample of both active and closed records; Y / N / NA
- the clinic's health care policies? Y / N / NA

5. Does the clinic's staff consider the findings of the evaluation? Is corrective action taken, if necessary? Y / N / NA

6. Is this documented? Y / N / NA

## **VIII. Pharmaceuticals**

1. Are drugs and biologicals appropriately stored? If stored in a refrigerator, is there a thermometer in the refrigerator to ensure that the temperature is acceptable? Y / N / NA
2. Are drugs and reagents checked routinely for expiration dates? Are they discarded when they are past their expiration dates? Y / N / NA
3. Do the drugs include emergency medications such as:
  - analgesics; Y / N / NA
  - anesthetics (local); Y / N / NA
  - antibiotics; Y / N / NA
  - anticonvulsants; Y / N / NA
  - antidotes and emetics; Y / N / NA
  - serums and toxoids. Y / N / NA

## **IX. Policies**

1. Does the clinic have written policies which include:
  - A description of the services the clinic furnishes directly, and those furnished through arrangement or agreement? Y / N / NA
  - Guidelines for the medical management of health care problems, including the conditions requiring medical consultation and/or patient referral? (This could include protocols for the mid-level practitioner.) Y / N / NA
  - Procedures for the periodic review and evaluation of the services furnished by the clinic? Y / N / NA
  - Rules for the storage, handling, and administration of drugs and biologicals? Y / N / NA
  - A clinical record system, including: written procedures which govern the use and removal of records from the clinic? the conditions for release of information? Y / N / NA
  - A preventive maintenance program, to ensure that the premises are clean and orderly, and that all essential mechanical, electrical, and patient care equipment is maintained in safe operating condition? Y / N / NA
  - Lines of authority and responsibility? Y / N / NA
2. Are the policies developed and periodically (at least annually) reviewed by a group of professional personnel that includes:

- one or more physicians; Y / N / NA
- one or more physician assistants or nurse practitioners; Y / N / NA
- one member who is not a member of the clinic's staff? Y / N / NA

3. Is this review documented in writing? Y / N / NA

**X. Physical Plant and Environment**

1. Is the clinic organized so as to provide safety and access to all patients? Y / N / NA

2. Is there adequate space for the patients to receive care? Y / N / NA

3. Are the premises clean and orderly? Y / N / NA

4. Are all surfaces where patient care items are stored varnished or painted with enamel so that the surfaces can be washed and sanitized, when necessary? Y / N / NA

5. Have illuminated exit signs been placed over all exits? Y / N / NA

6. Is there a written plan for evacuation in the event of a fire? Y / N / NA

7. Is there a plan for handling other problems such as power failure, water failure, blizzards, tsunamis etc.? Y / N / NA

8. Has the clinic staff been trained in handling non-medical emergencies, such as fire? Is this training documented? Y / N / NA

9. Is there documentation or other evidence of at least annual maintenance of mechanical, electrical, or patient care equipment? Y / N / NA How is appropriate equipment calibrated?

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9. Who is responsible?

Name: \_\_\_\_\_

10. Are current Infection Control (Universal Precautions) practices observed?

Y/N/NA

11. Are sharps disposed of in rigid, puncture-resistant containers? Y / N / NA

12. Are chemicals and cleaning solutions properly labeled? YIN INA